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Research Ethics in Accessing Hospital Staff and Securing Informed Consent

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Managing the ethics of the research process is not static practice. Observing guidelines for inquiry and international agreements on the dignity of health care research cannot ensure that the challenges and dilemmas inherent in the everyday management of a project are also regulated. In this article we discuss the continual negotiation of ethics in a qualitative research project; in particular we discuss access to participants and the construction of informed consent. Important contrasts emerged between the “ideal” presented for the standard ethics review process and ethics in practice bringing open communication and good project management across the life of a specific project into focus. When researchers’ interaction range from informed gatekeepers to different and numerous occupational groups and “accidental participants”, ethics become a “process”, and informed consent a fragile construct. We analyzed and wrote this article collaboratively to represent the empirical reality of a team of researchers collecting data in three National Health Service (NHS) Trusts in the United Kingdom and struggling to take ethics seriously.

data collection and management; ethics / moral perspectives; health care; qualitative analysis; research, access to participants

Qualitative researchers are required to manage the ethical aspects of any research project carefully. Furthermore, research conducted in health care settings faces particular ethical rules and standards, covered by both external and internal regulation. In developing and applying ethics to a particular professional context such as medicine and social research, ethical matters take on a distinctive form (Homan, 1991; Morse, 2010). In the case of social research, ethics have to be closely applied to “the realities of the research situation” (Homan, 1991, p. 1). By acknowledging that there is a “growing mismatch between increasingly standardized ethics procedures and the complex nature of qualitative research” (Miller, 2007), we argue that ethics should be approached as a “process” (Cassell & Young, 2002; Guillemin & Gillam, 2004; Cutcliffe, 2002; Miller & Bell, 2002; Ramcharan, 2001). Through examples, we demonstrate that “ethics as process” raises important considerations for research conducted in the health care setting as well as for qualitative research more broadly, especially regarding informed consent. In doing so, we raise valuable questions for health researchers and for Research Ethics Committee (REC) members.

Frank (2004) explains the difference between “ethics-as-substance” and “ethics-as-process”, by pointing out how in the first condition, ethics become a “specialty that some people do and it can be left to them”, whereas the latter recognizes “on-going negotiation” and the openness of ethics in decision making (p. 355). As we demonstrate in this article, “ethics-as-process takes on the messier, more complicated work of recognizing that multiple interests are each real and that any choice implicates multiple persons and groups” (Frank, 2004, p. 356).

Characteristic of contemporary discussion on ethical issues is a focus on the principle of informed consent: the notion that human subjects of research should be allowed to agree or refuse to participate in the light of comprehensive information concerning the nature and purpose of the research (Homan, 1991; see also World Medical Association Declaration of Helsinki, 2008). In addition to formal requirements and standardized procedures, such as

producing and signing consent forms, it is of fundamental importance that research participants understand what the research is about, who is undertaking and financing it, why it is being undertaken, and how it is to be promoted (British Sociological Association [BSA], 2002)¹. How, then, to convey this information in a way that is meaningful, to participants and to the researchers managing this process on a day-to-day basis, in a changing context with emergent ethical dilemmas?

In discussing the process of constructing informed consent within a qualitative study, Miller and Boulton (2007) suggest that the research community should share their experiences from the field; challenges, practicalities, and the decisions made. Furthermore, DeVries and Subedi (1998) suggest that researchers using empirical data and concrete documentation of the practice and implications of ethical decision-making in human research should move on to investigate “how ethical decisions are actually reached as opposed to how they should be reached” (p. v; see also Anderson & Sieber, 2006). In line with these suggestions, we present key dilemmas in accessing participants and seeking informed consent for a qualitative study within three National Health Service (NHS) hospital Trusts in the United Kingdom.

In our study, the constant negotiations for gaining access to participants, i.e., different health care professionals, proved to be a crucial component of securing inclusiveness and informed consent, whereas open communication was vital in guaranteeing the ethical progress of the project. The discussions focused on: (a) the project approval stage with a Research Ethics Committee (REC); (b) negotiations with gatekeepers to access participants; (c) challenges in the field.

The data presented in this article include ethnographical field notes and seminar presentation and focus group transcripts. Furthermore, the research team engaged in reflexive practices while in the field and in the data analysis processes, thus “aware of their own research activities” (Roberts, 2001, p. 3; see also Barry et al., 1999; Guillemin & Gillam, 2004;

Patterson, Hart, & Weaver, 2010)². The conclusions we drew present a set of good practices learnt through research encounters within the complex health care environment.

The Project: Leadership and Patient Care

The study explored the meanings and perceptions of relationships between leadership and patient care and how leadership is defined by key stakeholders and transmitted across organizations to impact on service delivery. We began from the premise that ‘leadership’, ‘patient care’ and ‘organisational change’ are not objective facts but social or discursive constructions. (Nicolson et al., 2011, p. 46; Parker, 2002) In other words, talk about leadership is the process by which leadership is constructed (and thus recognised) as something that happens in organisations such as the NHS.

We focused on three NHS Trusts which we considered manageable within the time frame and other resources available for the project. Data was collected between June 2007 and June 2010 in nine departments across five hospitals. The sample of the three Trusts was decided according to three criteria: a) they were each different from each other in the image they projected (on their websites, in terms of their physical style, locality, size and community) and that the sample had to include one Foundation Trust; b) they were in easy reach of London (for practical purposes because the study team were based in London and Surrey); c) we were able to gain access to the Trusts via personal contacts in Research & Development department or senior management (the gatekeepers). Sampling of research sites within each of the Trusts was achieved through negotiations with the gatekeepers and/or key informants recommended by the gatekeepers, with the intention that a balance might be struck between: the specific academic interests of the research team, some degree of opportunity for comparison between the Trusts, and the concerns of the gatekeepers and other senior Trust staff.

INSERT FIGURE 1. ABOUT HERE

The data collection methods included focus groups, individual semi-structured interviews, ethnographic observation and “shadowing” of key personnel (Bruni, Gherardi, & Poggio, 2004), as well as an adaptation of a pre-existing measure of organizational climate (Stringer, 2002). Participants included junior doctors, registrars and consultants, managers, clinical directors, midwives, and medical secretaries.

INSERT TABLE 1. ABOUT HERE

Our recruitment plan involved selecting participants for interviews and focus groups on an “informed” volunteer basis, via meetings with key informants and staff group presentations, which provided information about the study, offering staff an opportunity to participate. To recruit staff members who could not attend the meetings or presentations, thereby increasing the variety of staff groups and levels of seniority in our sample, we planned to send emails via a staff mailing list. However, hospital confidentiality issues impeded this research strategy, and prevented us from accessing the email lists. Therefore, mass communication was never actualized.

We decided the rules for engagement in ethnographic observation from a strategic (i.e., the staff and / or situation that would yield the richest source of information) and a pragmatic basis (i.e., the possibility of the situation yielding important data regarding leadership, organisational culture and climate and patient care). The observations of staff and patient-staff interactions required the participants to be familiar and comfortable with the presence of the researchers and familiar with the ongoing research process and also be prepared to co-operate. In the field (which in this case is a department in an NHS Trust) the researchers’ aim was to “understand how the cultures they are studying ‘work’” that is, to grasp “what the world looks like” to the participants in the context being observed (Delamont, 2004, p. 206).

Shadowing involved the same conceptual framework as ethnographic observation with the aim to understand what the world looked like from the perspective of the staff member being

shadowed as well as the worlds of the other staff and patients that they engaged with in the course of their work (Czarniawska, 2008; McDonald, 2005). This process involved meeting the participant (usually) at 8 am and for one or two days accompanying them at all times, including breaks until the participant went home. In Trusts where there was more than one site and/or when the nature of the day's work involved meetings outside the hospital (as in nearly every case) then the researcher spent time in a car with the participant and if mutually agreed the conversation was digitally recorded as an *aide memoire* for the field notes. The participant was thus able to withdraw at any time, or for a period of time, across the shadowing period.

In this study, observation and shadowing opportunities were (mostly) set up formally and pre-arranged. In addition, the researchers, through taking their roles as interviewers, focus group leaders through having an everyday presence with key informants, gatekeepers and participants, were able to immerse themselves in the lives and atmosphere of each of the Trusts and departments providing evidence about the processes of leadership and patient care as well as 'climate' (Bloor, 2001; Goffman, 1961). These methods allowed people to *physically* express their inner thoughts, and put ideas into observable action, all of which would have been inaccessible through the survey or interview questions.

The data collection, recruitment of participants and analysis took place simultaneously, capturing the interplay between leadership and patient care developed through close exploration of several sources of data. Similarly, we faced diverse ethical challenges that the use of each method brought about, which we addressed as the process unfolded.

The aim of the study being to research the relationship between leadership and patient care *in situ*, meant that ethics were very closely connected to the fieldwork itself. However, there was an aspect of disconnection between the management of the study (e.g., meeting deadlines, aims, answering research questions) and the management of ethics in a higher level. Although

the team had all had previous experience of fieldwork and an understanding of the nature of access negotiations in health care settings, the formal requirements of the study design had not taken account of the implementation issues researchers needed to be ready to address in qualitative research. Setting out to fulfil the promise of a research proposal it seemed was not a straightforward issue in health care research because the field could take even the most seasoned researchers by surprise.

In what follows, we discuss specifically the ethics processes that emerged during negotiating access to each hospital, including three seminar presentations to clinical staff members, piloting an Organizational Climate Survey, OCS (Stringer, 2002), focus group questions and a hospital tour. The main aim of this article is to describe how access to participants and informed consent was constantly negotiated and re-established during the qualitative data collection part of this study. A positive ethical review had been only a start to managing research in ethical way as we discovered.

Research Ethics Committees (RECs) and Qualitative Research

Traditionally, statements of research ethics principles in the social sciences have “drawn heavily on those developed within the medical profession” (Homan, 1991, p. 9; Tod, Nicolson, & Allmark, 2002). In the United Kingdom, hospital and health authority Research Ethics Committees, RECs, have existed in different forms since 1968. These committees follow the principles of the World Medical Association’s Helsinki Agreements and a standardized framework with inputs from the Department of Health and National Research Ethics Service, NRES. (Howard, 2004) Having a research proposal approved by a REC is required before conducting a study in any health care setting.

In addition to the procedural control of RECs over a research project, there are several professional bodies that provide “codes” or “guidelines” for social research, such as The British Sociological Association, BSA, and The British Psychological Society, BPS (Homan,

1991, p. 10). Individual university departments and schools also have their own ethical guidelines for staff members and students conducting research, that are often based on the research ethics framework by the Economic and Social Research Council, ESRC (see for example Hedgecoe, 2008; Wiles, Heath, Crow, & Charles, 2004), and there is also the National Institute for Health Research's Good Clinical Practice, an obligatory course for researchers who wish to conduct research in hospitals. In brief, the role of RECs is to review research proposals and set out specific standards to be met, whereas the ethical guidelines attend to complex ethics issues arising in the conduct of research.

Qualitative researchers have criticized RECs for using a regulatory model of research ethics based on the positivist tradition of biomedical research, taking for granted the existence of objective, universal truths and the "essentialised subject". This framework presumes a radically different epistemic standpoint, data collection methods and analysis than social sciences and humanities, in which research ethics policy and processes should provide "guidance but not definitive solutions to questions about ethical research and moral behavior" (Halse & Honey, 2005, p. 2147-2148). There are clear "epistemic tensions between the discourses of the universal, rational subject of scientific realism and those of the multidimensional, particular, and social subject of interpretative, qualitative research" (Halse & Honey, 2005, p. 2150). Instead of opting for objective "scientific neutrality", qualitative research pays attention to the research process as interactive enterprise. Thus, instead of submitting to "universal certainty that crafts an illusion that ethics approval means ethical research" the researchers in qualitative tradition reflect on the ways that "researchers think through ethical questions" (Halse & Honey, 2005, p. 2148).

Critics also question the ability of RECs to "judge" qualitative research (see for example Coleman, 2008; Dixon-Woods, Angell, Ashcroft, & Bryman, 2007; Halse & Honey, 2005; Howard, 2004; Murphy & Dingwall, 2007), and their authority. Even though critics

acknowledge the importance of some “form of monitoring” (Howard, 2007) and “the presence and importance of organizational processes, structures and constraints” (Kyarimpa & Garcia-Zamor, 2006), the current procedures are often perceived to be “intimidating” and “intrusive”, “an obligation that delays the “real” work of research, and “infamous for their rejection of research proposals” (Halse & Honey, 2005; Howard, 2007). In the current situation, “ethical gatekeepers”, such as RECs, perform an initial review of a study. However, during the course of the project, “the responsibility for ensuring that the research is conducted in an ethical manner rests with the researcher” (Daniel-McKeigue, 2007, p. 240). How, then, to involve RECs into the resolution of ethical dilemmas that are likely to emerge over the course of a qualitative research project, without establishing an even heavier regulatory structure?

Ells (2011) offers simple advice: to communicate better the study design and research plan to the research ethics review boards. A research team will need to refine the skills to explain procedures relating to qualitative methods prior to data gathering. This communication should include a description of the uncertainties that go with qualitative inquiry, and explain that unforeseeable situations are likely to arise in the field. To make the research setting more accommodating to all qualitative research, the ethics review board needs to adopt an open, exploratory attitude toward inductive research proposals. If a proposal does not include specific numbers for interviews or structured list of focus group questions, this is to be understood as an incompatible question with the research design, not automatically lack of expertise or unpreparedness of the researchers. In response, the researchers need to argue their case and present it in a coherent form within the field of qualitative inquiry, not having to employ quantitative research measures and templates (Ells, 2011). In the case of successful communication between qualitative researchers and an ethics review board, the accumulation of examples and experiences and establishment of common ground could lead into a situation in which the board shifts from being a disciplining institution to a stakeholder in the process.

The evaluation of a qualitative research proposal should focus on how researchers plan to manage their project to prevent harm and to manage ethical challenges that arise.

It is far from our intent here to disparage the expertise of REC members, but to emphasize how qualitative researchers themselves need to understand that however well-intentioned RECs are, their members are not necessarily the best people to decide on the “risks and benefits of their research” (Hedgecoe, 2008, p. 874; see also Ells, 2011). According to Hedgecoe’s (2008) ethnographic study of United Kingdom RECs, the members of the committees saw their role as “one of supporting or encouraging research, in addition to the more obvious duties of protecting patients and ensuring informed consent”, and they shared much of the “skepticism about the way in which qualitative research is or has been dealt with by such committees” (Hedgecoe, 2008, p. 874)³.

Because “goal posts” within (health care) organizations are constantly being moved, it is inevitable that researchers and participants will encounter unexpected ethical challenges during the course of a study. RECs, researchers, practitioners, and participant/consumer groups should discuss ethical procedures, making explicit the internal regulation of ethics by all the stakeholders. For example, researchers could provide RECs, post project, descriptions of situations in which they were required to take action to achieve or sustain ethical conduct. This would enable the RECs to develop a broader view into realities in the field and act as a mediator between projects and research teams, communicating examples of incidents to researchers with new proposals. Such dialogue would help to develop RECs into evidence based supporting institutions for qualitative researchers.

Informed Consent in Health Care Settings

Informed consent is at the heart of ethical concerns, because by conveying information about a project, and the questions and possible concerns raised by the gatekeepers and the participants, that a researcher is informed of the context specific ethics. “[O]rganisations are

internally characterised by ambiguity, ambivalence, and equivocality” (Czarniawska, 2005 cited in Dixon-Woods et al., 2007, p. 799) and therefore one template of ethics will not match all situations. In the following we discuss briefly how informed consent is perceived within health care research before moving on to describing how access to participants was negotiated and the project communicated within our study.

Informed consent is “a procedure widely agreed to safeguard the rights of human subjects to know that research is being conducted and to approve their own participation” (Homan, 1991, p. 2). In the context of health and social care research, ethics of data collection are often focused on disabled or vulnerable participants; for example, how to secure informed consent of hospital patients (see for example, Booth, 1999; Knox, Mok, & Parmenter, 2000; Ramcharan & Cutcliffe, 2002). The position of medical professionals within a study attracts less attention because they are construed as powerful and by definition able to make “rational informed choices” (Halse & Honey, 2005, p. 2145-2146). After all, these are the professionals who should strive to secure informed patient consent prior to medical procedures (see Brown, Butow, Butt, Moore, & Tattersall, 2004).

Because “research ethics is deeply embedded and implicated in the social context” (Halse & Honey, 2005, p. 2149), it is beneficial in the early stages of a study, to construct an understanding of the particular organization in question; how research projects are perceived in the participating units and departments, perhaps staff have been exhausted with numerous studies, or maybe there is an organizational restructuring taking place that affects the research outcomes. This will only become clear after the researchers have negotiated entry and spent some time in the field, developing sensitivity to the culture in question. Thus, the exposure to the field informs the researcher(s) on the context specific ethical considerations. This kind of information cannot be foreseen *per se*, but could be disclosed in the research proposal and discussed with the ethics review board as one of the initial stages of the investigation. The

positivistic ethics with universal claims (see for example Halse & Honey, 2005; Howard, 2007) can only guide a researcher in general terms, and the ethics within the culture/group being studied, and in the first place expressed by gatekeepers, deserve closer attention as they unfold.

Public service ethics can be “very broad” and “often ambiguous”, shaped by circumstances including the political and social contexts (Kyarimpa & Garcia-Zamor, 2006, p. 31-32). It can therefore be challenging to remain within a rigid framework of ethics when conducting research with participants who represent such a shifting organization as the NHS in the United Kingdom. Nevertheless, a more local ethics framework does not mean discarding all guidelines. As Kyarimpa and Garcia-Zamor (2006) note,

[I]n most public service organizations, patterns of basic assumptions predetermine and even control behaviors, thinking, performance, and decision making of individual members. These basic assumptions can take the form of values, beliefs, symbols, customs and rituals – thus constituting organizational culture that guides the performance of organizational members (p. 35).

Each qualitative study faces specific and situated ethical dilemmas, and at each stage of the research process researchers work through a variety of complications, searching for less harmful alternatives (see for example Burgess, 2007; Lincoln & Denzin, 2000; Denzin & Lincoln, 1994). In the following section we move on to describe and elaborate on two aspects within the study that became crucial in negotiating access to participants and enhancing informed consent: educational seminars and managing challenges in the field.

Communicating the Research Project to Participants

Even though consent needs to be reestablished on a regular basis (Ramcharan & Cutcliffe, 2002; Sin, 2005), the initial presentation of a study has an elementary role in recruiting

participants and establishing a research relationship. The talk that introduces a study can be viewed as an “active, consequential part of the interviewing process... such talk clearly provides precedence and direction” (Holstein & Gubrium, 1995, p. 41). Thus, the introduction “positions the respondent in relation to the questions that are about to be asked” (Holstein & Gubrium, 1995, p. 42).

In our study, this introduction comprised of educational seminars that we organized for the prospective participants. The participants of these three seminars had time to ask questions and act as a group, thereby making the purpose of the study and the intended proceedings open to challenge and transparent. These seminars also introduced an unexpected ethical problem in that they were not inclusive of all professions working in each unit. Researchers therefore had to launch additional negotiations to gain access and gatekeeper approval to the excluded groups.

Two of the staff seminars took place at a maternity unit in Trust 1. The first seminar included a presentation about our project including audience questions and piloting of the Organizational Climate Survey. The second session in Trust 1 involved a lecture about theories of leadership and focus group methodology, followed by participants’ questions and a focus group discussion. The introduction of the project in Trust 2 included a formal meeting with three gatekeepers and a walking tour of the hospital site in which the research team was introduced to other health professionals. The third educational seminar took place at Trust 3 and involved a presentation of leadership theories and the project with an emphasis on methodology to a mixed group of health professionals.

Trust 1: Two Seminars in an Obstetrics and Gynecology Department

Following approval by a REC, our team of seven, two Professors, three senior members of staff and two research assistants arranged for a meeting at a participating hospital. We had three hours to give a presentation and to pilot our survey. During the gathering two members

of the research team (Lokman and Rowland) took observational notes and part of the session was recorded, with the knowledge and agreement of all participants in the meeting, and later transcribed verbatim.

For the first seminar the group consisted of between 15-20 junior doctors, registrars and consultants⁴. The proceedings included a presentation on recent academic literature on leadership, given by the Chief Investigator of the project, (Nicolson), a case study for discussion presented by a senior member of the group and a pilot of the survey, which received some correction suggestions and clarification of terms. After the meeting, the participants were provided with the REC-approved participant information sheet about the project, a consent form and a researcher's business card with contact details. Some of the participants agreed an interview time on the spot.

This initial contact with a number of staff members proved to be an efficient way to recruit participants and to enhance informed consent. Indeed, seven people from this group participated in an interview and six in a focus group. However, only later did we realize the limitations of this seminar recruitment process. Although the main gatekeeper, with whom we were negotiating the practicalities, gave us the impression that this was an inclusive seminar for all staff members of the unit, this was not actually the case. Generally, it was only managers and senior clinicians who had been able to take the time out of clinical practice to attend these presentations and we discovered that nursing staff and midwives were routinely left out.

The second seminar in Trust 1 Maternity Unit was very different in nature and involved a smaller group of participants in a more intimate space. The group consisted of six junior doctors (3 women, 3 men) and the gatekeeper consultant who had arranged for the first educational seminar. Attendance to the seminar had been prearranged, because it was structured as part of the junior doctors' education. Within this meeting a senior member of the

research group gave a presentation on leadership approaches followed by a discussion and after that another team member facilitated a focus group. Some of the participants were not happy for a recorder to be used, so during the session two researchers (Lokman and Rowland) took observational notes which were subsequently subjected to rigorous discussion including comparisons of how the team members had made sense of the discussions⁵.

Initially, the consultant had dominated the responses in this focus group, but gradually the junior doctors became more involved, with one of the juniors having conflict with their supervisor. An interesting situation emerged when the consultant, after the presentation and discussions, decided to attend the focus group and then attempted to get the facilitator to complete the focus group prematurely because he had to leave. The consultant eventually agreed that the group of the junior doctors could continue without his presence. This was a prime example of a gatekeeper's power and ethics as a substance: "For clinicians, ethics designates a resource to be called on while doing daily, shop-floor work, as well as a system of accountability for this work... This ethics-as-substance can bring necessary safeguards to clinical work and improve some people's lives – it is often better than no ethics at all – but imagining ethics this way limits the scope of being ethical" (Frank, 2004, p. 355).

Whether the consultant was protecting his juniors from the researchers, or the unit leaders, including himself, from the prospect of receiving criticism, the consent was not his to give on behalf of the rest of the group⁶. This incident highlighted how ethical decisions cannot always wait for a committee to gather and make a recommendation. Fieldwork comes down to good project management, and the researchers' evaluation of the incident: are we causing harm? Should we discontinue data gathering? What do the actions of senior clinical staff giving consent on behalf of their junior colleagues tell about the culture, and, how should researchers' respond to this experience *in situ*? As Pearson (1992) notes, the process of negotiating access to the field and recruiting participants is data as such, because it is these

situations that tell us, for example, how this particular organization relates to the external environment and how it attempts to absorb non-members into its own way of looking at and interpreting the world. This educational seminar clearly demonstrated how gatekeeper power can extend beyond access negotiations into data collection.

Because we had already negotiated access to participants and communicated the study in Trust 1, we had been confident in approaching the second Trust, hoping that a similar style of presenting our research to prospective participants could be replicated. However, we quickly realized that there was no single template for negotiating access with gatekeepers or informing participants. Therefore each approach had to be tailored to each Trust, Department and professional group.

Trust 2: Formal Meeting and Walking Tour at Hospital A

The first formal meeting in Trust 2, consisting of two sites, A and B, was conducted by three gatekeepers; a senior nurse, a medical director and a director of emergency services, and attended by four members of the research team the Chief Investigator (Nicolson), a senior team member and two researchers (Fox and Rowland). The meeting was recorded via Dictaphone and later transcribed verbatim⁷.

In the meeting, Nicolson gave a presentation, which introduced the research team, an overview of the project, and the research methods. Following the presentation all three gatekeepers expressed their interest in the project and formally granted permission for the research to be conducted at the hospital. They also discussed the perceived value that they felt the research would bring to them on a personal level and to the Trust more broadly suggesting that they had their own agenda for approving the research⁸. Although the participants had openly expressed their interest to the researchers, the previous experience of situations in which some groups had been excluded from the project because of gatekeeper actions, provided the potential for the researchers to be alert to hidden agendas. These agendas could

have had an impact on access to, or coercion of, certain participant groups influencing informed consent (see Morrill, Buller, Buller, Larkey, 1999).

Walking Tour

After the meeting, the senior nurse and medical director led the research team on a walking tour of site A. The conversation during this was also recorded and transcribed verbatim. During the tour the gatekeepers introduced the research team to key health professionals and managers including consultants, acute physicians, matrons and general managers, all of whom granted permission for the researchers to contact them.

Although the research team was able to access to a greater number of participants through the walking tour, we had only been introduced to the most senior members of the department. This meant that the more junior potential research participants had not initially been informed about the research, which prevented the team from directly accessing them or at least meant that each attempt meant a detailed explanation of the research and reiteration that relevant approvals had been achieved. Senior health professionals therefore had to assist by arranging access to junior professionals, which could have potentially been understood to be participant coercion. This was a prime example how ethics as process works; by being aware of the excluded groups, the researchers had been able to plan more effective project management and, thus, increased the inclusiveness and ethical standard of the study.

Similar communication weakness arose at site B. Although the consultants and doctors had been informed of the project details through meetings, the nursing team had been absent from these meetings, and the information had not been adequately passed on. Therefore, when the researchers approached them to take part in the research they expressed anger at not being informed about the project and that decisions had been made on their behalf by the consultants and management team. This matter had to be resolved as quickly as possible and a presentation was arranged through one of our nursing contacts. The presentation was

conducted by two researchers (Fox and Rowland) to a group of 15-20 senior nurses during their training session. The presentation allowed the nurses to gain a sense of involvement and allowed them to provide their full informed consent to participate in the study. As Young et al. (2010) note, in seeking informed consent, it is highly important to “promote communication that establishes all participants as co-agents” (p. 629).

In Trust 2 the power of gatekeepers had created particular communication dilemmas for the research team, resulting in complex re-negotiations to enable access to participants. It became clear that the accumulation of organizational insights enhanced our sensitivity to ethical issues.

Trust 3: Shadowing and “Accidental Participants”

In Trust 3, a new ethical issue emerged, this time not involving gatekeepers, but what we have termed “accidental participants”. The communication of the prospective study commenced in Trust 3 as an educational seminar, organized by one of the Trust’s gatekeepers, a medical director. The presentation was conducted by the Chief Investigator (Nicolson) and a researcher (Rowland), and attended by a variety of health professionals; consultants, doctors, nurses and therapists including occupational, speech and physiotherapists of mixed grades. Unlike the similar process for Trust 1, this group seemed to operate as a cohesive and supportive team, which eliminated the sense of coercion surrounding informed consent.

The presentation was informal and health professionals asked questions and made comments throughout, suggesting their engagement with the project, and especially the ethnographic methodologies used. From the presentation, two consultants agreed to take part in ethnographic shadowing.

At the time of shadowing the consultants, the researchers did not have any fresh ethical concerns because the health professionals had fully consented to participate in the research. Instead, they were faced with a situation, where they had to make a decision on how to secure

the informed consent of “accidental participants”. Such participants were those patients, other health professionals, and bystanders who happened to be in the same room as the fully consented health professional who interacted with them (Mulhall, 2003; Wiles et al., 2004)⁹. The researchers discussed this ethical dilemma with the Chief Investigator and the research team and it was agreed that the health professional(s) being shadowed or observed would provide full informed verbal and written consent, whereas “accidental participants” would provide (where possible) informed verbal consent. “Accidental participants”, especially the patients and health professionals with whom the consented health professionals interacted, gave their verbal consent following introductions made by the observed health professional, for the research to continue in their presence. However, explaining the research to “accidental participants”, especially patients, was particularly difficult, in a way that was meaningful to them, because of time restrictions and the nature of the encounter itself. This raised questions about whether their consent was truly informed (see also Mulhall, 2003).

One researcher (Rowland) was also concerned that patients might have felt coerced into consenting because of the presence of and the introduction by the health professional treating them. However, some “accidental participants” declined consent indicating that they understood that their participation was voluntary in the research and that it had no bearing on their medical treatment (for discussions on vulnerable participants see for example Cassell & Young, 2002; Masson, 2004; Morrow, 1999; Stalker, 1998; Wiles et al., 2004). On these occasions the researcher did not take ethnographic notes, respecting the wishes of the “accidental participant”.

This situation demonstrates how researchers have to make ethical decisions in the field, and take responsibility for those judgments. McGibbon, Peter, and Gallop (2010) discuss the complex ethical implications in an ethnographic study taking place in a health care setting, noting the importance of obtaining consent from patients even though the study is being

conducted on the staff members. This includes ensuring that patients are aware of their right to refuse to have medical professionals observed while they are being cared for.

Discussion

This article focused on exploring the ethical challenges in negotiating access to and seeking informed consent within qualitative study on leadership and patient care in three hospital Trusts. First, we discussed the role of Research Ethics Committees, suggesting that for these regulatory bodies to become meaningful to stakeholders in a qualitative research project, there needs to develop a common understanding of what can be expected from a qualitative research proposal and how researchers should communicate this line of inquiry. In addition, we suggested that RECs could play an important role in forming an evidence-based ethics “library” for qualitative health research. Second, we illustrated biased informed consent through participant coercion and decision making and discussed the importance of good research management in the field. In our study, accessing participants transformed from being the anticipated straightforward issue of contacting staff members via email, into a series of educational seminars at hospital wards. These seminars provided invaluable data about each organization, but also resulted in frictions and raised excluded participants’ doubts toward the research team.

Research in the field gave rise to many ethical issues, but potential harm was limited by employing effective communication between the team members and to the participants. It was fundamentally important that researchers developed sensitivity toward the organizations to seek inclusion of different stakeholder groups and subgroups. During the three year project it became apparent, as Wiles et al. (2004) note, that we, as social researchers, had to balance a number of factors in managing access and informed consent. This included legal frameworks and regulation (REC), as well as a range of competing interests, such as “the aims of the research”, contested in educational seminars, “what they [researchers] consider to be the best

interests of research participants” (Wiles et al., 2004, p. 11), such as in the case of accidental participants, and the interests of formal or informal gatekeepers, as was explicitly the case in Trust 2.

Conclusions

In this article, we described some of the ethical dilemmas our research team faced during a three-year project studying leadership and patient care in three NHS hospital Trusts. We began with a discussion on the role of Research Ethics Committees (REC) in evaluating a qualitative project, because they represent the formal body of ethical approval, and because emphasizing ethics as a static collection of standards is in stark contrast with our experience of ethics as process. To shift the perceived role the RECs occupy today as a disciplining committee of positivist school of thought, we recommended two things: qualitative researchers need to communicate (educate) their audience through the presentation of a proposal that is “true to their research” (Ells, 2011, p. 886). Thus, instead of, for example, using hypotheses or projected aspirations for data collection (number of participants, interviews, focus groups, and observations), describing a situation or briefly introducing a case study would be more aligned to an inductive approach.

Our main aim has been to discuss ethics as process on two levels: for qualitative research in general and more specifically within the health care setting. However, some of the findings could be valuable in other areas of research. The introduction of the project through staff seminars proved to be an effective way of communication, although we would like to emphasize the importance of careful management of these occasions. Also, lessons learnt from the study include the acknowledgement of gatekeepers’ power when it comes to accessing participants in health care settings. This is worth noting, for example, when recruiting patients for clinical epidemiological studies.

Based on our findings in the field, we argue that because power differences between gatekeepers and networks in complex organizations such as the NHS, some (occupational) groups inevitably become construed as “vulnerable” in ethical terms. Our multi-method, multisite project required constant negotiations of access, recruiting participants and ensuring that information was as widely and openly distributed as possible. Thus, *ethics is a process*, and for it to be conducted effectively we suggest ensuring the inclusiveness of all stakeholders in any preparatory meeting and seminar and maintaining communication throughout the project.

Notes

1. In the United Kingdom there is an increasing demand by ethics committees for researchers to produce written consent forms; Read and Maslin-Prothero (2010) note how this taken for granted ethics procedure can become problematic for researchers who would like to include in their study people with limited cognition, or who cannot read or write (p. 708; see also Morse, 2010).
2. Researchers informed the Chief Investigator (Nicolson) about any scheduled meetings at hospitals, and disclosed descriptions of events (verbal or email messages) in the following days. Data transcripts and field notes were circulated among the team, allowing all members to provide feedback and advice regarding, for example, the refinement of data collection tools. Researchers also shared an office, which enabled the constant comparing of notes and experiences, and planning of activities. Discussing through difficult situations, e.g., a researcher being denied from conducting an agreed focus group and sent abruptly out the room by a senior clinician, or the anger excluded staff groups expressed toward the project, became an important part of communication within the project.
3. Our qualitative study received ethics approval with no opposition from a Research Ethics Committee in February 2007. The board members asked enthusiastic and encouraging

questions rather than “hostile” ones (see Hedgecoe, 2008). The paperwork was evaluated positively (see Wiles et al., 2004 for a discussion on written research information), and when the committee posed questions about the hospital departments we were to study, such as whether they would be like-for-like across the hospitals, they were satisfied with the answer that, within an inductive research project, these kinds of practicalities would unfold as we enter the field and become more familiar with each context.

4. The participant numbers varied during the seminar, because beepers went off regularly, and people constantly left or entered the room.

5. The nature of ‘ethics-as-process’ thus required that the team of researchers, who have their own perceptions and experiences derived from the fieldwork (especially in an ethnographic enterprise), discuss ethical dilemmas within the group, before any conclusions are drawn.

6. A similar incident took place with a nurses’ focus group, when some of the participants disclosed that they did not have any prior information about the study, but were sent to take part of the occasion by their managers. These highly dubious actions came close to ‘proxy consent’, which is sometimes used in research with ‘vulnerable’ groups who are viewed as lacking the capability or ‘competence’ to understand what participating in a study will involve and so are unable to provide informed consent for themselves (Wiles et al. 2004: 18).

7. The director of emergency services consented to an interview and to be shadowed for two days, one day at site A and the other at Site B. The senior nurse agreed to an interview and the medical director consented to two days of ethnographic shadowing.

8. The process nature of ethics in the field was evident in this situation; the participants stated their interests to the researchers, being engaging and transparent. However, based on our experience, we understood that gatekeepers having their own agendas regarding the project might entail ethical dilemmas, which could only be resolved as the events unfolded and the study progressed.

9. Researchers observing health professionals in relation to their patient face similar dilemmas to studies of teachers being observed in classrooms. Ideally, informed consent should also be obtained from students as a teacher's behavior cannot be observed independently of student's reactions. However, there is a difference in the organizational context, which limited the foreseeing of the situation in hospitals. Pupils are permanent fixtures in a classroom, whereas the participants of our study were truly accidental in the respect that their (e.g., physiotherapists, porters) presence often could not be predicted and in the case of patients, they were continually changing.

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References

- Anderson, E. E. & Sieber, J. E. (2006). The need for evidence-based research ethics: A review of the substance abuse literature. *Drug and Alcohol Dependence*, 86, 95-105. doi:10.1016/j.drugalcdep.2006.06.011
- Barry, C.A., Britten, N., C. Barber, C. Bradley, & Stevenson, F. (1999). Using reflexivity to optimize teamwork in qualitative research. *Qualitative Health Research*, 9, 6-44. doi: 10.1177/104973299129121677

Bloor, M. (2001). The ethnography of health and medicine. In Atkinson, A. C. P. , Delamont, S., Lofland, J., and Lofland, L. (Eds.), *Handbook of Ethnography* (pp. 177- 187). London: Sage.

Booth, W. (1999). Doing research with lonely people. *British Journal of Learning Disabilities*, 26, 132 – 134. doi: 10.1111/j.1468-3156.1998.tb00068.x

Bruni, A., Gherardi, S. & Poggio, B. (2004). Doing gender, doing entrepreneurship: An ethnographic account of intertwined practices. *Gender, Work & Organization*, 11, 406–429. doi:10.1111/14680432200400240

British Sociological Association. (2002). *Statement of Ethical Practice for the British Sociological Association*. Retrieved from:
<http://www.britisoc.co.uk/NR/rdonlyres/801B9A625CD3-4BC2-93E1-FF470FF10256/0/StatementofEthicalPractice.pdf>

Brown, R. F., Butow, B. N., Butt, D. G., Moore, A. R., & Tattersall, M. H. N., (2004). Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials. *Social Science & Medicine*, 58, 379-390.
doi:10.1016/j.socscimed.2003.09.007

Burgess, M. M. (2007). Proposing modesty or informed consent. *Social Science & Medicine* 65, 2284-2295. doi:10.1016/j.socscimed.2007.08.006

Cassell J. & Young, A. (2002). Why we should not seek individual informed

consent for participation in health services research. *Journal of Medical Ethics*, 28, 313-317. doi: 10.1136/jme.28.5.313

Coleman, C. H. B. & Bouesseau, M-C. (2008). How do we know that Research Ethics Committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Medical Ethics*, 9, 1-7. doi:10.1186/1472-6939-9-6

Cutcliffe, J. R. & Ramcharan, P. (2002). Leveling the playing field? Exploring the merits of the ethics-as-process approach for judging qualitative research proposals. *Qualitative Health Research*, 12, 1000-1010. doi: 10.1177/104973202129120313

Daniel-McKeigue, C. (2007). Cracking the ethics code: What are the ethical implications of designing a research study that relates to therapeutic interventions with children in individual play therapy? *The Arts in Psychotherapy*, 34, 238-248. doi:10.1016/j.aip.2007.02.001

deVries, R. & Subedi, J. (1998). (Eds.) *Bioethics and Society: Constructing the Ethical Enterprise*. Lebanon, Indiana, USA: Prentice Hall.

Dixon-Woods, M., Angell, E., Ashcroft, R. E., & Bryman, A. (2007). Written work: The social functions of Research Ethics Committee letters. *Social Science & Medicine*, 65, 792-802. doi:10.1016/j.socscimed.2007.03.046

- Ells, C. (2011). Communicating qualitative research study designs to research ethics review boards. *The Qualitative Report*, 16, 881-891. Retrieved from <http://www.nova.edu/ssss/QR/QR16-3/ells.pdf>
- Frank, A. W. (2004). Ethics as process and practice. *Internal Medicine Journal*, 34, 355–357. doi: 10.1111/j.1445-5994.2004.00622.x
- Goffman, E. (1961). *Encounters: Two studies in the sociology of interaction*. Oxford: Bobbs-Merrill.
- Guillemin, M. & Gillam, L. (2004). Ethics, reflexivity, and “ethically important moments” in Research. *Qualitative Inquiry*, 10, 261-280. doi: 10.1177/1077800403262360
- Halse, C. & Honey, A. (2005). Unraveling ethics: Illuminating the moral dilemmas of research ethics. *Signs*, 30, 2141-2165. Retrieved from <http://www.refdoc.fr/Detailnotice?idarticle=7539315>
- Hedgecoe, A. (2005). “At the point at which you can do something about it, then it becomes more relevant”: Informed consent in the pharmacogenetic clinic. *Social Science & Medicine*, 61, 1201-1210. doi:10.1016/j.socscimed.2005.01.021
- Homan, R. (1991). *The Ethics of Social Research*. London and New York: Longman.
- Howard, D. (2004). Gaining approval for research in health and social care in the UK. *Journal of Orthopaedic Nursing*, 8, 109-113. doi:10.1016/j.joon.2004.02.001

- Knox, M., Mok, M., & Parmenter, T. R. (2000). Working with the experts: collaborative research with people with an intellectual disability. *Disability and Society*, 15, 49 – 61. 10.1111/j.1468-3156.2004.00281.x
- Kyarimpa, G. E. & J-C, Garcia-Zamor (2006). The quest for public service ethics: Individual conscience and organizational constraints. *Public Money and Management* 26, 31-38. Doi: 10.1111/j.1467-9302.2005.00498.x
- Mauthner, M., Birch, M., Jessop, J. & Miller, T. (2002). *Ethics in qualitative research*. London, Thousand Oaks, New Delhi: Sage Publications.
- McGibbon, E., Peter, E., & Gallop, R. (2010). An institutional ethnography of nurses' stress. *Qualitative Health Research* 20, 1353. doi: 10.1177/1049732310375435
- Miller, T. & Bell, L. (2002). Consenting to what? Issues of access, gate-keeping and “informed consent”. In Mauthner, M., Birch, M., Jessop, J. & Miller, T. (Eds.), *Ethics in qualitative research* (pp. 53-69). London, Thousand Oaks, New Delhi: Sage Publications.
- Miller, T. M. B. (2007). Changing constructions of informed consent: Qualitative research and complex social worlds. *Social Science & Medicine*, 65, 2199-2211. doi:10.1016/j.socscimed.2007.08.009

Morrill, C., Buller, D. B., Buller, M. K., & Larkey, L. L. (1999). Toward an organizational perspective on identifying and managing formal gatekeepers. *Qualitative Sociology*, 22, 51-72. doi: 10.1023/A:1022183232593

Morse, J. M. (2010). How different is qualitative health research from qualitative research? Do we have a subdiscipline? *Qualitative Health Research* 20, 1459.
doi: 10.1177/1049732310379116

Mulhall, A. (2003). In the field: notes on observation in qualitative research. *Journal of Advanced Nursing*, 41, 306-313. doi: 10.1046/j.1365-2648.2003.02514.x

Murphy, E. D. & Dingwall, R. (2007). Informed consent, anticipatory regulation and ethnographic practice. *Social Science & Medicine* 65, 2223-2234.
doi:10.1016/j.socscimed.2007.08.008

Nicolson, P., Rowland, E., Lokman, P., Fox, R., Gabriel, Y, Heffernan, K.,
Howorth, C., Ilan-Clarke, Y. and Smith, G. *Leadership and Better Patient Care: Managing in the NHS*. Final report. NIHR Service Delivery and Organisation programme; 2010.

Parker, I. (2002). *Critical Discursive Psychology*. Basingstoke: Palgrave.

- Patterson, S. E., Hart, J., & Weaver, T. D. (2010). Delusions and Qualitative Confusions: A Dialogic Collaborative Exploration. *Qualitative Health Research*, 20, 1008-1018. doi: 10.1177/1049732310363805
- Ramcharan, P. & Cutcliffe, J. R. (2002). Judging the ethics of qualitative research: Considering the 'ethics as process' model. *Health and Social Care in the Community*, 9, 358-366. doi: 10.1046/j.1365-2524.2001.00323.x
- Read, S. & Maslin-Prothero, S. (2010). The involvement of users and carers in health and social research: The realities of inclusion and engagement. *Qualitative Health Research*, 21, 704-713. doi: 10.1177/1049732310391273
- Reeves, C. L. (2010). A difficult negotiation: fieldwork relations with gatekeepers. *Qualitative Research*, 10, 315-331. doi: 10.1177/1468794109360150
- Robson, C. (2002). *Real world research*. Oxford: Blackwell.
- Sin, C. H. (2005). Seeking informed consent: Reflections on research practice. *Sociology*, 39, 277-294. doi: 10.1177/0038038505050539
- Stringer, R. (2002). *Leadership and Organisational Climate*. New Jersey: Prentice Hall.

Tod, A., Nicolson, P. & Allmark, P. (2002). Ethical review of health service research in the UK: Implications for nursing. *Journal of Advanced Nursing*, 40, 379-386. doi: 10.1046/j.1365-2648.2002.02385.x

Wiles, R., Heath, S., Crow, G. & Charles, V. (2004). Informed Consent in Social Research: A Literature Review. ESRC National Centre for Research Methods. *NCRM Methods Paper Series*. Retrieved from <http://eprints.ncrm.ac.uk/85/1/MethodsReviewPaperNCRM-001.pdf>

World Medical Association Declaration of Helsinki. (2008) *Ethical Principles for Medical Research Involving Human Subjects*. Retrieved from <http://www.wma.net/en/30publications/10policies/b3/index.html>

Young, A. J., Kim, L., Li, S., Baker, J. N., Schmidt, M., Camp, J. W., & Barfield, R. C. (2010). Agency and Communication Challenges in Discussions of Informed Consent in Pediatric Cancer Research. *Qualitative Health Research*, 20, 628-643. doi: 10.1177/1049732310361467

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Table 1. Research Data by Modes of Collection

Trust	Interviews	Focus Groups	Shadowing	Ethnographic Observation	Other meetings and site visits
	Women (w) Men (m)	Groups (participants)	N=Days	N=Days	
1	19 (w) 13(m)	5 (15)	5	9	4
2	9 (w) 5 (m)	3 (24)	8	1.5	2
3	8 (w) 4 (m)	0 (0)	13	0	2
Total	26 (w) 22 (m)	8 (39)	26	11.5	8

Figure 1: Flowchart demonstrating research sites for each Trust

